

Dkt No. PP01468.103

Serial No. 09/187,661

AMENDMENTIn the Claims:

CJ

1. (Currently amended) A low salt-containing aqueous composition comprising biologically active human IGF-I or a biologically active variant thereof in a concentration of ~~at least~~ about 250 mg/ml or greater and a pH ~~greater than about~~ of pH 5.0 or greater, wherein said variant is a polypeptide that has at least 80% amino acid sequence identity to the amino acid sequence of human IGF-I.

2. (Previously canceled)

3. (Previously amended) The composition of claim 1, wherein said human IGF-I or variant thereof is present in a concentration of about 250 mg/ml to about 500 mg/ml.

4. (Previously amended) The composition of claim 1, wherein said human IGF-I or variant thereof is present in a concentration of about 350 mg/ml, and wherein said composition has a density of about 1.07 g/ml and a viscosity of about 15,700 cps.

5-7. (Canceled)

8. (Previously canceled)

9-11. (Canceled)

12. (Previously canceled)

13. (Previously amended) A kit for reconstituting a pharmaceutical composition comprising biologically active human IGF-I or biologically active variant thereof, said kit comprising the composition of claim 1 and separately a pharmaceutically acceptable buffered solution having a pH less than or equal to pH 5.0.

Dkt No. PP01468.103

Serial No. 09/187,661

14-15. (Canceled)

02 16. (Currently amended) A pharmaceutical composition comprising the composition of claim 1, and a pharmaceutically acceptable carrier ~~and/or excipient~~.

17. (Original) The pharmaceutical composition of claim 16, wherein said composition is a sustained-release formulation.

18. (Original) The pharmaceutical composition of claim 16, wherein said composition is a gel formulation.

19. (Previously amended) A cryogenically produced PLGA microsphere comprising the composition of claim 1.

20. (Previously amended) The microsphere of claim 19, wherein said microsphere comprises a lyophilized form of said composition.

21-27. (Canceled)

28. The composition of claim 1, wherein said variant differs from the amino acid sequence for said human IGF-I by up to 5 amino acid residues.

29. The composition of claim 1, wherein said variant differs from the amino acid sequence for said human IGF-I by up to 2 amino acid residues.

30. The composition of claim 1, wherein said variant differs from the amino acid sequence for said human IGF-I by 1 amino acid residue.

31. The composition of claim 1, wherein said human IGF-I is recombinant human IGF-I.

32. The composition of claim 1, wherein said recombinant human IGF-I is present at a concentration of about 250 mg/ml to about 500 mg/ml.

Dkt No. PP01468.103
Serial No. 09/187,661

33. The composition of claim 1, wherein said recombinant human IGF-I is present at a concentration of about 350 mg/ml, and wherein said composition has a density of about 1.07 g/ml and a viscosity of about 15,700 cps.

CB 34. (Currently amended) A low salt-containing aqueous composition comprising biologically active human IGF-I in a concentration of ~~at least~~ about 250 mg/ml or greater and a pH ~~greater than about~~ of pH 5.0 or greater.

35. The composition of claim 34, wherein said human IGF-I is recombinant human IGF-I.

36. The composition of claim 34, wherein said human IGF-I is present at a concentration of about 250 mg/ml to about 500 mg/ml.

37. The composition of claim 34, wherein said human IGF-I is present at a concentration of about 350 mg/ml, and wherein said composition has a density of about 1.07 g/ml and a viscosity of about 15,700 cps.

38. (Previously amended) A pharmaceutical composition comprising the composition of claim 34, and a pharmaceutically acceptable carrier and/or excipient.

39. A cryogenically produced PLGA microsphere comprising the composition of claim 34.

40. (Previously amended) A pharmaceutical composition comprising the composition of claim 37, and a pharmaceutically acceptable carrier and/or excipient.

41. A cryogenically produced PLGA microsphere comprising the composition of claim 37.

cy 42. (Currently Amended) A low salt-containing aqueous composition comprising biologically active recombinant human IGF-I is a concentration of about

Dkt No. PP01468.103

Serial No. 09/187,661

Cy Donchale
350 mg/ml, and wherein said composition has a density of about 1.07 g/ml and a viscosity of about 15,700 cps and a pH [greater than about] of pH 5.0 or greater.

43. (Previously amended) A pharmaceutical composition comprising the composition of claim 42, and a pharmaceutically acceptable carrier and/or excipient.

44. A cryogenically produced PLGA microsphere comprising the composition of claim 42.

CS
45. (New) A pharmaceutical composition comprising the composition of claim 1, and a pharmaceutically acceptable excipient.

46. (New) The pharmaceutical composition of claim 45, wherein said composition is a sustained-release formulation.

47. (New) The pharmaceutical composition of claim 45, wherein said composition is a gel formulation.
